DETAILED ACTION

1. Applicants amendment to the claims, filed on August 4, 2009, is acknowledged.
Claims 1-16 have been canceled.
Claims 17-63 are pending.

Applicant's election of Group III (drawn to an anti-CD22 antibody) and the species of SEQ ID NOs: 7, 11-14, 16, 20, and 21, filed on August 4, 2009, is acknowledged. The traversal is on the ground that the anti-CD22 antibody in Group III and the nucleic acid in Group IV share the common function of CD22 binding and structure of the parent antibody RFB4. In addition, applicant argues that Groups V and VI encompassing the use of the anti-CD22 antibody in Group III. Thus, applicant asserts that the restriction requirement should be withdrawn.

This is not found persuasive for reasons of record. In addition, this application includes claims to more than one product and process. When an application includes more than one product, process, or apparatus, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the "main invention" (see MPEP 1850). Based on 37 CFR 1.475, an international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and a process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
(4) A process and an apparatus or means specifically designed for carrying out the said process; or
(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process

In this case, the anti-CD22 antibody in claims 17-42 and 61-63 is considered to have unity of invention together with the first method of using the anti-CD22 antibody encompassed in Group V (including claims 50-57).

Applicant's rejoinder request of antibody and all method of use in Groups III, V, and VI is acknowledged. As discussed supra, the antibody in Group III and the first method of use of said antibody in Group V are examined together herein. The second method of use of the antibody in Group VI will not be rejoined herein since not all claims to the product are found allowable (see discussion below).

The restriction requirement is deemed proper and is made final.

Consequently, claims 43-49 and 58-60 have been withdrawn from further consideration, under 37CFR 1.142(b), as being drawn to nonelected inventions.

Claims 17-42, 50-57, and 61-63 are currently under consideration as they read on the elected anti-CD22 antibody comprising CDRs of SEQ ID NOs: 7, 11-14, 16, the VL chain of SEQ ID NO:20 and the VH chain of SEQ ID NO:21.

2. Applicant's IDS, filed on September 8, 2008, is considered.

3. Claims 23, 31, 35, 36, 41, 42, 52, 56, and 57 are objected to for following informalities:

Claims 23, 31, and 52 recite "Kabat Numbering shown in Figure 2 and 3".

Given that Kabat numbering system is well known in the art for referring the positions of the amino acid residues in an antibody, it is not necessary to rely upon the description or drawings of the instant application. Application is suggested to delete "known in Figure 2 and 3".

Claims 35, 36, 41, 42, 56 and 57 recite "at a position corresponding to position 490 of SEQ ID NO:24". Applicant is suggested to amend the claims to "at position 490" for clarity.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 35, 36, 41, 42, 56, and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 35, 41, 42, 56, and 57 are indefinite in the recitation of "PE35, PE38, PE38KDEL, PE40, PE4E, and PE38QQR" because their characteristics are not known. The use of "PE35, PE38, PE38KDEL, PE40, PE4E, and PE38QQR" as the sole means of identifying the claimed mutated *Pseudomonas exotoxin* A renders the claims indefinite because the terms are merely laboratory designations which do not clearly define the claimed products, since different laboratories may use the same designations to define completely distinct biological materials.

It is noted that the specification discloses the amino acid sequence of PE38 in SEQ ID NO:22. Amending the claims to recite the SEQ ID NOs for each of the PE variants recited can obviate this rejection.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06.

B) Claim 36 recites the limitation "wherein said arginine residue at a position corresponding to position 490 of SEQ ID NO:24 is replaced by alanine". There is insufficient antecedent basis for this limitation in the claim.

For examination purposes, claim 36 is read as dependent upon of claim 35.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 35, 36, 41, 42, 56, and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 35, 36, 41, 42, 56, and 57 are drawn to a chimeric molecule comprising an anti-CD22 antibody and mutated PE selected from the group consisting of "PE35, PE38, PE38KDEL, PE40, PE4E, and PE38QQR" wherein said mutated PE has a glycine, alanine, valine, leucine or isoleucine in position 490 of SEQ ID NO:24.

The instant specification is not sufficient to enable a skilled artisan to practice the claimed invention without conducting an undue amount of experimentation.

The specification discloses that the amino acid sequence of PE38 is SEQ ID NO:22 (e.g. see paragraph [0160] on page 43 of the instant specification). However, SEQ ID NO:22 consists of three hundred and forty-five amino acid residues. It is not clear how mutated PE, e.g. PE38, can have a residue such as glycine in position 490 of the SEQ ID NO:24 as claimed. Further, the specification discloses that the recited PE mutants were described in prior art; for example, the specification states that the mutant containing KDEL is taught by US Patents 5,854,044, 5,821,238, and 5,602,095 (e.g. see paragraph [0160] on pages 43-44). However, upon review of these US Patents, the disclosure of PE35, PE38KDEL, PE40, PE4E, and PE38QQR is not readily apparent.

Applicant has claimed truncated PE forms "PE35, PE38, PE38KDEL, PE40, PE4E, and PE38QQR". The specification discloses that the PE can be modified to reduce or eliminate non-specific cell binding by deleting domain Ia, 1b, some portions of domain II, or by mutating certain residues of domain Ia (see pages 43-44). However, the specification does not appear to provide sufficient guidance as to which structural regions of PE are amenable to sequence variation without loosing the biological property of the PE. As such, a skilled artisan would be unable to make and use the full breadth of applicant's claimed PE35, PE38KDEL, PE40, PE4E, and PE38QQR without first conducting additional research.

Applicant is suggested to amend the claims to recite specific amino acid sequences of the claimed PE mutants.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06.

8. Claims 17-34, 37-40, 50-55, and 61-63 are objected to because they contain non-elected species and would be allowable if the claims are re-written to commensurate to the elected species of SEQ ID NOs: 7, 11-14, 16, 20, and 21 and obviate any objection stated above.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Ram Shukla can be reached 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chun Dahle/
Examiner, Art Unit 1644